

Notice of Allowability	Application No.	Applicant(s)	
	09/780,653	QASBA ET AL.	
	Examiner	Art Unit	
	Joseph T. Weitach	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 11/14/2005.
2. ☒ The allowed claim(s) is/are 4 and 5.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

DETAILED ACTION

This application is a continuation of 09/316,797, filed May 21, 1999, which claims benefit to 60/086,420, filed May 22, 1998 and 60/108,308, filed November 13, 1998.

Applicants' amendment filed November 15, 2005 has been entered. Claims 4 and 5 have been amended. Claims 1-3 have been canceled. Claims 4-8 are pending.

Election/Restriction

Applicant's election of group II, claims 4 and 5, in Paper No. 3, was acknowledged. It was noted that because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 4-8 are pending. Claims 6-8 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Claims 4 and 5 are currently under examination.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4 and 5 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn.

The amendment to the claim to recite “enriched” instead of “purified” has addressed the basis of the rejection. As indicated previously, support for “enriching” (page 6) and general means of isolating known in the art at the time of filing (methods of Haynesworth *et al.*, (1992) on page 12).

Claims 4 and 5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating a subject in need of megakaryocytes as platelet precursor cells comprising administering to said subject autologous or allogenic bone marrow in an amount effective to produce megakaryocytes, does not reasonably provide enablement for administering only mesenchymal stem cells or mesenchymal stem cells and CD34+ cells alone is withdrawn.

The amendment to the claims and Applicants’ arguments have obviated the basis of the rejection. As acknowledged previously, the present disclosure demonstrates the affect of mesenchymal stem cells on CD34+ cells. Without further evidence, the skilled artisan would

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expect the same or similar affect in a subject. With respect to administration, methods consistent with the delivery of bone marrow would be supported by the instant specification, and enabled fro affecting the method as claimed. With respect to subjects where megakaryocytes are needed, the skilled artisan would be aware of such clinical indications, and in the context of the present disclosure where providing mesenchymal stem cells or mesenchymal stem cells and CD34+ cells would provide benefit to a patient.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4 and 5 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

The amendment to the claims to delete “purified” and to recite “enriched” has obviated the rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 4 and 5 rejected under 35 U.S.C. 102(b) as being anticipated by Lemoli *et al.* (Acta Haematologica 95:164-170, (1996)) as evidenced in Developmental Biology (page 357) is withdrawn.

The amendments to the claims has differentiated the claimed invention from that specifically disclosed and supported by Lemoli *et al.*

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Examiner's Amendment

As indicated throughout prosecution, Applicant's election of group II, claims 4 and 5, in Paper No. 3, was acknowledged. It was noted that because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

This application is in condition for allowance except for the presence of claims 6-8 directed to inventions non-elected without traverse. Accordingly, claims 6-8 have been cancelled.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

Cancel claims 6-8.

Reasons for Allowance

The following is an examiner's statement of reasons for allowance:

The present disclosure is the first to demonstrate the specific affect of mesenchymal stem cells on the differentiation of CD34+. More specifically, the present disclosure provides evidence that while CD34+ cells have the capacity to differentiate into a wide variety of cell types, when cultured in the presence of mesenchymal stem cells differentiate preferentially down the pathway to become megakaryocytes. This disclosure provides the basis for the instantly claimed invention, where these observations are applied to a clinical setting to affect treatment in a subject.


Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach


JOSEPH WOITACH, PhD
PRIMARY EXAMINER
AU 1632